UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

N. Bhushan Mandava
Mandava Associates, LLC
Agent for Repar Corporation
1050 Connecticut Avenue, NW, Suite 1000
Washington, DC 20036

Subject: Suspension of Repar's Registrations of Pesticide Products Containing Pendimethalin (EPA Reg. Numbers: 69361-29, -30, -31, -32) for Failure to Comply with the Pendimethalin Registration Review Data Call-In Notice Dated May 30, 2013

Dear Mr. Mandava:

This letter gives you notice, as the agent for Repar Corporation, that the pesticide product registration listed in Attachment I will be suspended 30 days from your receipt of this letter unless you take steps within that time to prevent this Notice from automatically becoming a final and effective order of suspension. The Agency's authority for suspending the registrations of your products is section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Upon becoming a final and effective order of suspension, any violation of the order will be an unlawful act under section 12(a)(2)(J) of FIFRA.

You are receiving this Notice of Intent to Suspend because you have failed to comply with the terms of the Registration Review Data Call-In Notice (GDCI-108501-1267) imposed pursuant to section 4(g)(2)(B) and section 3(c)(2)(B) of FIFRA. The specific basis for issuance of this Notice is stated in the Explanatory Appendix (Attachment III) to this Notice. The affected product and the requirement which you failed to satisfy are listed and described in the following three attachments:

Attachment I	Suspension Report - Product List
Attachment II	Suspension Report - Requirement List
Attachment III	Suspension Report - Explanatory Appendix

The suspension of the registration of each product listed in Attachment I will become final unless at least one of the following actions is completed.

1. You may avoid suspension under this Notice if you or another person adversely affected by this Notice properly request a hearing within 30 days of your receipt of this Notice. If

you request a hearing, it will be conducted in accordance with the requirements of section 6(d) of FIFRA and the Agency's Procedural Regulations in 40 CFR Part 164.

Section 3(c)(2)(B), however, provides that the only allowable issues which may be addressed at the hearing are whether you have failed to take the actions which are the bases of this Notice and whether the Agency's decision regarding the disposition of existing stocks is consistent with FIFRA. Therefore, no substantive allegation or legal argument concerning other issues, including but not limited to the Agency's original decision to require the submission of data or other information, the need for or utility of any of the required data or other information or deadlines imposed, any allegations of errors or unfairness in any proceedings before an arbitrator, and the risks and benefits associated with continued registration of the affected product, may be considered in the proceeding. The Administrative Law Judge shall by order dismiss any objections which have no bearing on the allowable issues which may be considered in the proceeding.

Section 3(c)(2)(B)(iv) of FIFRA provides that any hearing must be held and a determination issued within 75 days after receipt of a hearing request. This 75-day period may not be extended unless all parties in the proceeding stipulate to such an extension. If a hearing is properly requested, the Agency will issue a final order at the conclusion of the hearing governing the suspension of your product.

A request for a hearing pursuant to this Notice must 1) include specific objections which pertain to the allowable issues which may be heard at the hearing, 2) identify the registrations for which a hearing is requested, and 3) set forth all necessary supporting facts pertaining to any of the objections which you have identified in your request for a hearing. If a hearing is requested by any person other than the registrant, that person must also state specifically why he asserts that he would be adversely affected by the suspension action described in this Notice. Three copies of the request must be submitted to:

Hearing Clerk, 1900
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

An additional copy should be sent to the signatory listed below. The request must be received by the Hearing Clerk by the 30th day from your receipt of this Notice in order to be legally effective. The 30-day time limit is established by FIFRA and cannot be extended for any reason. Failure to meet the 30-day time limit will result in automatic suspension of your registration by operation of law and, under such circumstances, the suspension of the registration for your affected product will be final and effective at the close of business 30 days after your receipt of this Notice and will not be subject to further administrative review.

The Agency's Rules of Practice at 40 CFR 164.7 forbid anyone who may take part in deciding this case, at any stage of the proceeding, from discussing the merits of the proceeding ex parte with any party or with any person who has been connected with the

preparation or presentation of the proceeding as an advocate or in any investigative or expert capacity, or with any of their representatives. Accordingly, the following EPA offices, and the staffs thereof, are designated as judicial staff to perform the judicial function of EPA in any administrative hearings on this Notice of Intent to Suspend: the Office of the Administrative Law Judges, the Office of the Environmental Appeals Board, the Administrator, the Deputy Administrator, and the members of the staff in the immediate offices of the Administrator and Deputy Administrator. None of the persons designated as the judicial staff shall have any ex parte communication with trial staff or any other interested person not employed by EPA on the merits of any of the issues involved in this proceeding, without fully complying with the applicable regulations.

2. You may also avoid suspension if, within 30 days of your receipt of this Notice, the Agency determines that you have taken appropriate steps to comply with the section 3(c)(2)(B) Data Call-In Notice. In order to avoid suspension under this option, you must satisfactorily comply with Attachment II, Requirement List, for each product by submitting all required supporting data/information described in Attachment II and in the Explanatory Appendix (Attachment III) to the following address (preferably by certified mail):

Office of Pesticide Programs
Pesticide Re-evaluation Division (PRD) (7508P)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

For you to avoid automatic suspension under this Notice, the Agency must also determine within the applicable 30-day period that you have satisfied the requirements that are the bases of this Notice and so notify you in writing. You should submit the necessary data/information as quickly as possible for there to be any chance the Agency will be able to make the necessary determination in time to avoid suspension of your product.

The suspension of the registration of your company's products pursuant to this Notice will be rescinded when the Agency determines you have complied fully with the requirements which were the bases of this Notice. Such compliance may only be achieved by submission of the data/information described in the attachments to the signatory below.

Your product will remain suspended, however, until the Agency determines you are in compliance with the requirements which are the bases of this Notice and so informs you in writing.

After the suspension becomes final and effective, the registrant subject to this Notice, including all supplemental registrants of products listed in Attachment I, may not legally distribute, sell, use, offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver, to any person, the products listed in Attachment I.

Persons other than the registrant subject to this Notice, as defined in the preceding sentence, may continue to distribute, sell, use, offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver, to any person, the products listed in Attachment I.

Nothing in this Notice authorizes any person to distribute, sell, use, offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver, to any person, the products listed in Attachment I in any manner which would have been unlawful prior to the suspension.

If the registration for your products listed in Attachment I is currently suspended as a result of failure to comply with another section 3(c)(2)(B) Data Call-In Notice or Section 4 Data Requirements Notice, this Notice, when it becomes a final and effective order of suspension, will be in addition to any existing suspension, i.e., all requirements which are the bases of the suspension must be satisfied before the registration will be reinstated.

You are reminded that it is your responsibility as the basic registrant to notify all supplementary registered distributors of your basic registered product that this suspension action also applies to their supplementary registered products and that you may be held liable for violations committed by your distributors.

If you have any questions about the requirements and procedures set forth in this suspension Notice or in the subject section 3(c)(2)(B) Data Call-In Notice, please contact Neil Anderson at (703) 308-8187.

Sincerely yours,

Richard P Keigwin, Jr

Richard P. Keigwin, Jr., Director
Pesticide Re-evaluation Division

Attachments:
Attachment I - Product List
Attachment II - Requirement List
Attachment III - Explanatory Appendix

Cc: Kable Davis, Product Manager, Registration Division
Philip Ross, Senior Attorney, Office of General Counsel

APPENDIX I - PRODUCT LIST

EPA Registration Number:	Product Name
69361-29	Pendim Weed and Feed
69361-30	Pendimethalin Technical
69361-31	Pendim 3.3 EC Herbicide
69361-32	Pendim H_2O Herbicide

Appendix II

Outstanding Pendimethalin Supporting Documentation

1) 90-Day DCI Response
2) Offer to cost-share
   or
   Certification of Attempt to Enter into an Agreement with Registrants for Development of Data (EPA Form 8570-32)

Outstanding Pendimethalin GDCI Data:

Guideline 835.4100—Aerobic soil metabolism

Guideline 835.6100—Terrestrial field dissipation

Guideline 835.6200—Aquatic field dissipation

Guideline 850.1350—Mysid chronic toxicity test

Guideline 850.1400—Fish early-life stage toxicity test

Guideline 850.2100—Avian acute oral toxicity test

Guideline 850.4100—Terrestrial plant toxicity (seedling emergence)

Guideline 850.4150—Terrestrial plant toxicity (vegetative vigor)

Non-guideline—Whole sediment: chronic invertebrates (freshwater and marine)

EXPLANATORY HISTORY - APPENDIX III

On May 31, 2013, the Agency issued the Registration Review Generic Data Call-In (GDCI-108501-1267) Notice for pendimethalin pursuant to section 3(c)(2)(B) of FIFRA, which required the registrants of products containing pendimethalin used as an active ingredient to develop and submit certain data. The data/information were determined to be necessary to satisfy the registration review requirements of section 3(g). Failure to comply with the requirements of a GDCI is a basis for suspension under section 3(c)(2)(B) of FIFRA.

On September 3, 2013, N. Bhusan Mandava, agent for Repar Corporation, submitted a 90-day DCI response to the Agency. In summary, Repar's response included the following elements:

(a) Repar submitted a Certification of Attempt to Enter into an Agreement with Registrants for Development of Data in order to cost share with other pendimethalin registrants for the following data requirements:
   - Guideline 835.6200—Aquatic field dissipation
   - Guideline 850.1350—Mysid chronic toxicity test
   - Guideline 850.1400—Fish early-life state toxicity test
   - Non-guideline—Whole sediment chronic invertebrates (freshwater and marine)

(b) Repar cited existing data submitted by BASF Corporation (BASF) in support of the pendimethalin Reregistration Eligibility Decision (RED) for the following data requirements:
   - Guideline 835.4100—Aerobic soil metabolism
   - Guideline 850.4100—Terrestrial plant toxicity (seedling emergence)
   - Guideline 850.4150—Terrestrial plant toxicity (vegetative vigor)
   - Guideline 850.2100—Avian acute oral toxicity; and

(c) Repar said it would upgrade a previously submitted study for guideline 835.6100—Terrestrial field dissipation, but did not indicate which of the previously submitted terrestrial field dissipation studies it intended to upgrade.

On September 13, 2013, Khue Nguyen of the Agency contacted Mr. Mandava, by both phone and email, to notify him that Repar's 90-day DCI response was inadequate and inappropriate. Ms. Nguyen told Mr. Mandava that the data Repar cited from the pendimethalin RED in order to fulfill guidelines 835.4100, 850.4100, 850.4150, and 850.2100 had already been reviewed by the Agency and determined to be insufficient to satisfy the registration review data needs. The pendimethalin problem formulation memorandum, titled *Registration Review: Preliminary Problem Formulation for Environmental Fate and Ecological Risk, Endangered Species, and Drinking Water Assessments for Pendimethalin (case 187)*, dated August 30, 2012, had already discussed the registration review data needs and discussed deficiencies in studies already submitted

to the Agency (the problem formulation memorandum has been and is publicly available in docket EPA-HQ-OPP-012-0219 at www.regulations.gov). The Agency requested by email and on the phone that Repar submit a revised 90-day DCI response and Mr. Mandava agreed to do so during the phone call.

On October 28, 2013, Ms. Nguyen emailed Mr. Mandava to inquire about the revised 90-day DCI response, which had not been submitted despite Mr. Mandava's stated intention to do so during the September 13, 2013 conversation. Mr. Mandava responded on October 30, 2013 and stated that he had attempted to contact Drexel Chemical, United Phosphorous Inc, and BASF regarding cost-sharing for data generation, but did not receive any response from them. Mr. Mandava admitted that he failed to do any follow-up work after the government shutdown in October. Mr. Mandava promised to attend to the matter when he got back from a conference the following week. Ms. Nguyen emailed Mr. Mandava back on October 30, 2013 and gave him a deadline of November 13, 2013 to submit a revised DCI response. On November 19, 2013, Ms. Nguyen emailed Mr. Mandava, told him that the November 13, 2013 deadline had passed, and warned him that failure to submit a revised DCI response will result in the issuance of a Notice of Intent to Suspend for Repar's pendimethalin products. Further, the Agency's email stated that Repar had until December 3, 2013 to submit the revised DCI response or the Agency would initiate the suspension process.

On December 4, 2013, Ms. Nguyen called Mr. Mandava to inquire about the overdue 90-day DCI response and reiterated what she had told him on September 13, 2013—that the RED data submitted by BASF could not be used to satisfy the DCI. During the conversation, Mr. Mandava promised to submit a revised 90-day DCI response the next week after he got back from a conference. On December 12, 2013, Ms. Nguyen emailed Mr. Mandava to reiterate the December 4, 2013 conversation and remind him that the Agency was beginning to pull together the elements for a Notice of Intent to Suspend. On December 16, 2013, Mr. Mandava emailed back and stated that Repar had "some reservations at this time about submitting a revised response to the DCI" and "would consider accepting your regulatory option--which is the Notice of Intent to Suspend at this time."

On February 12, 2014 (the letter was misdated as February 12, 2013), the Agency sent Mr. Mandava a letter outlining Repar's options for addressing the requirements of the pendimethalin DCI. Repar was given the following options:

1) Commit to conduct the required studies, conduct the required studies, and submit the studies in the timeframe established by the May 30, 2013 date of DCI issuance, or
2) Offer to cost-share with companies that have committed to conduct and are conducting the required studies and submit documentation to support election of that option, or
3) Request a voluntary cancellation of Repar's pendimethalin registrations pursuant to Section 6(f) of FIFRA, or

4) Request an amendment to Repar's pendimethalin registrations that prohibits any sale, distribution, and use until EPA has determined that Repar has satisfied all DCI requirements for its affected pendimethalin products and the prohibition provision has been removed from the registrations by the Agency.

The Agency noted that failure to select and support a listed option would result in the issuance of the Notice of Intent to Suspend for Repar's pendimethalin registrations. Mr. Mandava responded in letter to the Agency on March 31, 2014 and stated that "Repar has considered all four options outlined in the Agency's letter. At this time, Repar decided not to choose any of those options. Therefore, Repar leaves it to the Agency to impose an appropriate regulatory action under FIFRA Section 3(c)2(B)".

In addition, on March 7, 2014, BASF informed the Agency that "*BASF received no written offer to pay* from Repar committing to share in the costs of the BASF studies that Repar seeks to rely upon to satisfy the DCI requirements, contrary to Repar's certification on September 3, 2013." In its March 7, 2014 letter, BASF also petitioned the Agency to issue a Notice of Intent to Suspend Repar's affected products.

To date, an adequate and appropriate 90-day response to the pendimethalin Data Call-In Notice has not been received by the Agency from Repar Corporation or its designated agent. Therefore, this Notice of Intent to Suspend is being issued.